REMARKS

The Official Action dated June 20, 2007 has been carefully considered. Accordingly, the present Amendment is believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claims 9-21 and 23-29 are cancelled and claims 30-36 are presented. Support for these claims may be found throughout the present specification and original claims. It is believed that these changes do not involve any introduction new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, claims 9-21 and 23-29 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification. The Examiner asserted that the phrase "in an individual known to be allergic" recited in claim 9 and "in an individual known to be allergic, from a variety of possible allergen sources" recited in claim 23 represent a departure from the specification and claims as originally filed.

This rejection is traversed and reconsideration is respectfully requested. However, to expedite prosecution, claims 30-36 presented herein omit the phrases which the Examiner asserted departed from the original specification and claims. Accordingly, the rejection under 35 U.S.C. §112, first paragraph, has been overcome. Reconsideration is respectfully requested.

Claims 9-21 and 23-29 were rejected under 35 U.S.C. §112, first paragraph, on the basis that the specification is not enabling for and does not describe a method for serologically identifying with improved accuracy in all individuals known to have any allergy the actual sensitizing allergen source from a variety of possible allergen sources. On the other hand, the Examiner acknowledged at pages 4 and 8 of the Official Action that the present specification enables and describes a method for serologically identifying *Parietaria* allergic patients with improved accuracy among individuals previously known to be weed

pollen allergic by contacting the serum from the individual with Par j 1 or Par j 2, determining the presence of IgE binding thereto and identifying the individual as allergic to *Parietaria* species if the serum contains the IgE binding to Par j 1 or Par j 2.

This rejection is traversed and reconsideration is respectfully requested. Specifically, Applicants submit that claims 30-36 are now directed to the subject matter which the Examiner admitted as enabled by and described in the specification, whereby the rejections have been overcome. Reconsideration is respectfully requested.

Claims 9-21 and 23-29 were rejected under 35 U.S.C. §102(b) as being anticipated by Duro et al, *FEBS Letters*, 399 (1996), 295-298. The Examiner previously asserted that Duro et al teach contacting serum with recombinant Par j 2 to detect pollen allergy and that the characterization of the recombinant antigen is a preliminary step for use of the protein therapeutically. The Examiner concluded that the prior art teaches all of the method steps of the claimed invention and therefore anticipates the claimed invention as the preamble adds no additional limitations to the claims since the same product was used in the same method steps for identifying allergens from patients. The Examiner further asserted that Duro et al teach identifying the actual sensitizing allergen (recombinant Par j 2) from a variety of possible allergen sources since Duro et al teach there are nine possible allergens in the P. judaica pollen and since the Par j 2 is the allergen selected among all allergens to perform the experiments. The Examiner also asserted that if the Par j 2 is a pure allergen component, without cross-reactivity, with use as a diagnostic tool for diagnosing specific allergy, then this information shows that 18% of the patients were not allergic to P. judaica and therefore the results inherently show that 18% of the patients were allergic to another allergen from a variety of allergen sources other than P. judaica, presumably with cross-reacting proteins or epitopes to P. judaica.

In response to Applicants' previous arguments that Duro et al are not making a determination among allergen sources, the Examiner relied on the present specification and claims to establish that Par j 2 is diagnostic of *Parieta judaica* pollen allergen (sentence bridging pages 13 and 14 of Official Action). Additionally, the Examiner asserted that Duro et al need not teach that Par j 2 is non-cross-reactive with other polypeptides from other allergen sources since it is not presumed that it would cross-react, given that it is not the exact same peptide as that from other allergen sources, the Examiner further asserting that it is well known that peptides have specific properties that are related to their length and sequence and that it is highly unpredictable that two peptides that lack 100% length and sequence identity will have the same properties so that properties of a given protein or peptide are novel and specific to that protein or peptide, unless evidence is presented to the contrary. The Examiner does not cite any evidence of record to support these assertions.

However, Applicants submit that the methods defined by claims 31-36 are not anticipated by and are patentably distinguishable from the teachings of Duro et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 30, the invention is directed to a method for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic, comprising contacting serum from an individual known to be weed pollen allergic with a pure Par j 1 or Par j 2 allergen component, determining the presence of IgE binding to said pure Par j 1 or Par j 2 allergen component; and identifying the individual as *Parietaria* allergic if the contacted serum contains IgE binding to said pure allergen component.

Thus, the present methods are for accurately identifying a *Parietaria* allergic individual, particularly when the individual is known to be generally weed pollen allergic. Applicants have determined that *Parietaria* pollen extract binds IgE from individuals not

exposed to *Parietaria* pollen, while the recited pure allergen component Par j 1 or Par j 2 does not bind to IgE from such individuals. However, Par j 2 does bind IgE from most allergic individuals who are primarily sensitized to *Parietaria* pollen, as does Par j 1. Thus, Applicants have developed the present methods for specific identification of *Parietaria* allergic individuals from those known to be weed pollen allergic.

Applicants submit that Duro et al fail to teach a method for serologically identifying an individual known to be weed pollen allergic as *Parietaria* allergic. That is, the Duro et al publication is directed to a single allergen source, namely *Parietaria judaica* pollen, and does not mention other allergen sources or individuals known generally to be weed pollen allergic. While Duro et al seek to characterize one of at least 9 allergen components of this source, namely Par j 2, Duro et al are not concerned with any other allergy source. Further, by showing that 82% of the *Parietaria judaica* pollen sensitive patients' serum had IgE reacting with rPar j 2, Duro et al merely show that Par j 2 is a major allergen (see page 297, right column, lines 18-21), and no other findings or conclusions are provided by Duro et al. Particularly, Duro et al do not teach or suggest that Par j 2, or any other pure allergen component, can be employed in order to serologically identify with improved accuracy a *Parietaria* allergic individual from a general weed pollen allergic individual, as recited in the present claims.

The Examiner previously stated "if the Par j 2 is a pure allergen component without cross-reactivity...then this information shows that 18% of the patients were not allergic to P. judaica." However, Duro et al provide no teaching or suggestion that Par j 2 is a pure allergen component with limited or no cross-reactivity. In response to the previously submitted Declaration Under 37 C.F.R. 1.132 of the co-inventor Dr. Paolo Colombo, confirming that the Duro et al paper does not disclose or suggest that the Par j 2 allergen has limited or no cross-reactivity with allergen components from other weed pollen allergen

sources (paragraph 4) and thus does not teach or suggest using Par j 2, or any other purified allergen component, in methods for diagnosis of the actual sensitizing source from a variety of possible allergen sources (paragraph 4), the Examiner asserted that Applicants' own specification and claims show that Par j 2 is diagnostic of *Parietaria judaica* pollen allergy. However, the teachings of Applicants' specification and claims is not available as prior art to interpret what the Duro et al teachings would mean to one of ordinary skill in the art. As Duro et al do not teach or suggest that Par j 2 is a pure allergen component with limited or no cross-reactivity, and therefore suitable for use in identifying an individual to be weed pollen allergic as *Parietaria* allergic, Duro et al do not disclose a method for such identification.

Only in light of Applicants' specification can the Examiner conclude that the 18% of patients having serum which do not react with Par j 2 are inherently not allergic to *Parietaria judaica* and therefore must be allergic to another allergen from another allergen source while the 82% of patients having serum that reacts with Par j 2 are *Parietaria* allergic. Contrary to the Examiner's assertion that Duro et al need not "teach" that Par j 2 is non-cross-active, Applicants submit that Duro et al must provide this very teaching in order for one of ordinary skill in the art to employ Par j 2 in a method for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic.

As noted previously, the Examiner has asserted, without any support in the evidence of record, that it is well known that peptides have specific properties that are related to their length and sequence and that it is highly unpredictable that two peptides that lack 100% length and sequence identity will have the same properties. The Examiner concludes from these assertions that the properties of a given protein or peptide are novel and specific to that protein or peptide unless evidence is presented to the contrary. The Examiner's statements are not only unsupported on the record, they are contrary to the well known knowledge in the art of the cross-reactivity of pollens. In this regard, the Examiner's attention is directed to

Aalberse et al, *Allergy*, 56:478-490 (2001) which discusses the cross-reactivity of IgE antibodies and particularly states "Homologous proteins from phylogenetically related grasses tend to be cross-reactive" (page 478, left column, lines 11-13), and Weber, *J. Allergy Clin. Immunol.*, 112 (2):229-239 (2003) which discusses in detail the cross-reactivity of pollens. Accordingly, Applicants have established, contrary to the Examiner's unsupported assertions, that weed pollens are well known to be cross-reactive. Thus, the failure of Duro et al to teach that Par j 2 is non-cross-reactive demonstrates that Duro et al do not teach the presently claimed methods for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic.

Duro et al disclose the cloning and characterization of the allergen Par j 2.0101, and generally mention that in a diagnostic/therapeutic approach, a preliminary step is to purify and characterize each major allergen. This is only a general statement relating to all allergens and all diagnostic and therapeutic strategies. Applicants find no teaching or suggestion regarding any specific diagnostic method or approach. Particularly, Applicants find no teaching or suggestion by Duro et al regarding a method for accurately identifying a *Parietaria* allergic individual.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference. *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q. 2d 1949, 1950 (Fed. Cir. 1999). In view of the failure of Duro et al to teach a method for serologically identifying an individual known to be weed pollen allergic as *Parietaria* allergic, particularly by use of a pure Par j 1 or Par j 2 allergen component having limited or no cross-reactivity, Duro et al do not anticipate the methods of claims 30-36. Accordingly, the rejection under 35 U.S.C. §102 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§102 and 112, first paragraph, and places the present application in condition for allowance. Reconsideration and an early allowance are requested. In the event that the Examiner finds that a telephone discussion may assist in progressing the present prosecution, she is respectfully requested to contact the undersigned.

Please charge any fees required in connection with the present communication, or credit any overpayment, to Deposit Account No. 04-1133.

Respectfully submitted,

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